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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GAKH, YELENA G	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/945,003	HAALAND, PETER D.	
	Examiner	Art Unit	
	Yelena G. Gakh, Ph.D.	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-17,19,20 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-17,19,20 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed on 07/06/04 is acknowledged. Claims 1-28 are pending in the application. Claims 3-4, 18, 21-22 and 24-28 are withdrawn from the consideration. Claims 1-2, 5-17, 19-20 and 23 are considered on merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 1, 6-7, 11, 14, 17, 19, and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which applicant regards as the invention.

Claims 1 and 19 recite "a method for monitoring a biological property" with further recitation of "a biological input". It is not clear from the claim, if the biological property is related to the biological input, since no correlation is recited in the claim. Therefore, it is not clear, how the "method for monitoring a biological property" can be performed, if the biological property is not even mentioned ion the body of the claims. It is also not clear, how "converting the second signal into a human-discernable message" can contribute into "monitoring the biological property", since it is not clear, how this second signal is related to the biological property. The same is true for claim claim 17, for which it is not clear, what are relations between all four signals and the biological property to be monitored.

Claim 1 further recites "collecting a biological input", where the "biological input" can be both physiological liquid (claim 5) and a physical parameter (claim 6). With such incompatible groups of "biological input" it is not clear, what is claimed in the parent claim, since "collecting a physiological liquid" and "collecting a physical parameter" are different processes, which require completely different techniques. Moreover, in the case of physiological liquid it is not clear, how is it possible to "convert" it into a signal?

Claim 14 is indefinite, since the expression "physiological signal" is not clear and unambiguous; it is defined in the specification as such a variety of possible physical and biological features, that it makes it unclear, what type of the input port can fulfill the requirement of claim 14?

In claim 17 it is not clear, what is the biological property, for which a second biological input is required? The language of the claim makes it unclear and indefinite.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. **Claims 1-2, 5-17, 19-20 and 23** are rejected under 35 U.S.C. 102(b) as being anticipated by Lee (US 4,838,275) or David et al. (US 5,441,047).

Lee discloses method and system for monitoring a biological property as following: "in each patient's home is an apparatus that includes special furniture on which the patient lies and sits, and embedded in which are devices that automatically sense multiple parameters related to the patient's health. The patient cooperates only passively. The parameters are so chosen--and are sufficiently numerous and accurate--as to provide in the aggregate a comprehensive profile of the patient's general state of health. The apparatus also generates electronic health-parameter signals related to the sensed parameters, and it transmits these signals from the patient's home to a central surveillance and control office. Equipment there receives the signals, displays corresponding indicia of the parameters, and transmits control signals back to the patient's apparatus. Two-way voice communication between the patient and a highly trained observer at

the central office supplements the electronic measurements. The observer conducts routine diagnostic sessions except when an emergency is noted from these sessions or from a patient-initiated communication. The observer determines whether a nonroutine therapeutic response is required, and if so facilitates such a response. Selection among emergency cases follows a highly refined emergency-priority hierarchy" (Abstract). "This invention allows for detailed physiological surveillance in the patient's home. Blood pressure, heart rate, ECG, respiration rate and depth, center-of-gravity shifts, weight, temperature, breathing sounds, shivering, conversational characteristics, average blood glucose, and relative cardiac output can be monitored" (col. 5, lines 23-29).

David discloses "an ambulatory (in the home) patient health monitoring system ..., wherein the patient is monitored by a health care worker at a central station, while the patient is at a remote location. The patient may be a person having a specific medical condition monitored or may be an elderly person desiring general medical surveillance in the home environment. Cameras are provided at the patient's remote location and at the central station such that the patient and the health care worker are in interactive visual and audio communication. A communications network such as an interactive cable television is used for this purpose. Various medical condition sensing and monitoring equipment are placed in the patient's home, depending on the particular medical needs of the patient. The patient's medical condition is measured or sensed in the home and the resulting data is transmitted to the central station for analysis and display. The health care worker then is placed into interactive visual communication with the patient concerning the patient's general well being, as well as the patient's medical condition. Thus, the health care worker can make "home visits" electronically, twenty-four hours a day" (Abstract). "The present invention provides two-way interactive visual communications between the patient and the central station. The invention also provides for the monitoring by the central station of any of a number of possible vital signs and diagnostic test data. By way of example and not limitation, the vital signs to be monitored may include blood pressure, temperature, weight, heart rate, respiratory rate, oximetry and so on. At the present, two-way interactive cable television, with its widespread network, provides a two-way communication network suitable for use in the present invention. Its interactive nature provides the personal, visual contact between the patient and the staff located at the monitoring center. Moreover, this communication system

provides almost unlimited monitoring time. These attributes enable the collection of a multitude of medical data for prolonged periods of time, as well as the human contact that constitutes an important factor in the care of the population in need for such services. The long-term storage of medical and visual information helps in diagnosis and treatment. The transmission of the visual information and the monitored medical data between the central station and the patient's home may be made by satellite, radio transmission or through telephone lines, instead of cable television lines" (col. 5, lines 18-42).

6. **Claims 1-2, 5-17, 19-20 and 23** are rejected under 35 U.S.C. 102(e) as being anticipated by any of Avitall et al. (US 6,171,237 B1), Bro (US 6,249,809 B1) or Knapp (US 6,278,999 B1).

Avitall discloses method and system for monitoring a biological property: "a computer control system operates with an instruction set to provide automated administration of health care to a patient. In a preferred embodiment of the invention a central monitoring station receives data from a plurality of remote testing units. Each of the testing units is custom configured for a particular patient and is made to provide optimal care for that individual alone. Similarly one monitoring unit may serve multiple patients and transmit the data to a central monitoring computer via the telephone lines. Medical procedures are then administered to the patient and results taken as data. The data is made available to the central monitor so that proper medical interpretation is enabled. A number of novel steps in the programming of the system are taken to assure that the right patient is being monitored, that the patient is being tested properly and that the system is being monitored appropriately" (Abstract). "More particularly, the invention is directed to a condition monitoring system which includes one or more remote modular testing units and a central station. The remote units include physiological parameter testing modules to acquire data from one or possibly many patients and communicate with a central station typically capable of interfacing with a large number of patient-operated units or clinician-operated units testing many patients. The central station, in turn, may interface and communicate with any number of other devices as by networking. Parameters checked may include but are not limited to blood pressure, pulse rate, blood oxygen saturation, weight, blood glucose, temperature, prothrombin (clotting) time and pulmonary function, including respiratory rate and depth. Other functions, such as ECG (electro-cardiograph) traces and infant breathing

monitoring for detection of SIDS (sudden infant death syndrome) onset are also contemplated" (col. 1, lines 13-30).

Bro teaches a method and a system for monitoring a biological property which includes "means for measuring and recording various medical tests including a patient's weight, blood pressure, glucose, etc., and transmitting the test results information via the telecommunication wire or wireless system, and/or a magnetic card reader which can store medical or other information which can be transmitted via the telecommunication system" (col. 4, lines 26-33).

Knapp discloses a method for monitoring a biological property using telecommunication with specific emphasis on the ways of transferring information: "he present information management system for personal health digitizers. This system provides a centralized database that collects and stores monitoring data from a large number of individuals who are termed "consumers" herein. The information management system for personal health digitizers includes processing elements that can be used to perform statistical analysis of the collected data on a per consumer, population segment, or query specific basis. The analysis function is made available to various classes of "users" which classes can include consumers, medical practitioners, health care providers, institutions, and the like. The database is architected in a hierarchical manner to enable the users to access only the relevant, prepartitioned segment of the collected data that this particular class of user is authorized to analyze. Thus, the privacy of the consumer data is maintained by prohibiting access to this individuals data except to users who are specifically authorized by the consumer. In addition, the granularity of the data made available to the various classes of users is selected to prevent the users from deriving information about the consumer population that they are not entitled to receive" (Abstract). "The fact that home use biosensors are increasingly sophisticated and diverse as well as affordable attests to a large market opportunity that will continue to expand, as personal information about the condition of one's body acquired in the privacy of the home empowers the user relative to appropriate health care decision-making. Sensors that provide digital data, unlike analog test strip devices or mercury thermometers, open up the possibilities inherent in digital data analysis, storage, transmission, etc. The above-noted OvuSense product is representative of this new class of home-use digital-readout biosensors, which are termed Personal Health Digitizers (PHD's) herein" (col. 1, lines 66-67, col. 2, lines 1-10).

Response to Arguments

7. Applicant's arguments filed 07/06/04 have been fully considered but they are not persuasive. Rejections under 35 U.S.C. 112, second paragraph. The examiner cannot agree with the Applicant's statement "there is no rule that says the elements of the body of a clams must correlate to the preamble". Rule 35 U.S.C. 112, second paragraph says: "the specification shall conclude with one or more claims *particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention*". If there is no correlation between preamble, which gives a definition of the claimed invention, and the body of the claim, which recites this invention, then the claims do not "particularly point out and distinctly claim the subject matter, which the applicant regards as his invention". Claims 1 and 19 recite "a method for monitoring a biological property", however no biological property is recited in the body if the claims. This raises the question of how could the method for monitoring a biological property be performed, if this biological property is not even mentioned in the claims?

Further, combining such incompatible "biological inputs" as physiological liquids (recited in claim 5) and physical parameters (physiological signals, images, or response, recited in claim 6, which are indefinite terms on their own) the Applicants make it indefinite and unclear of what steps of "collecting" and "converting" the biological input may include. Not only will they require completely different steps of "collecting" and "converting", which makes the parent claim 1 indefinite as to what is meant by these terms, but it is also quite difficult to imagine converting such biological input as urine or blood "into a first signal".

Applicant's arguments with respect to rejections over the prior art have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yelena G. Gakh
09/07/04